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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,773	07/20/2004	Karl Kolter	53272	8423
26474 7590 06/04/2007 NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005			EXAMINER HAIDER, SAIRA BANO	
			ART UNIT 1711	PAPER NUMBER
			MAIL DATE 06/04/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,773	Applicant(s) KOLTER ET AL.	
	Examiner Saira Haider	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,6,8,9,12-19 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,7,10,11,20 and 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The indicated allowability of claim 11 is withdrawn in view of the newly discovered reference(s) to Babaian et al. (US 4842854). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 2, 5, 10, 20, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotsche (WO/00/18375) (Page: Lines:: 1:5-12, 4:3-11, 19:10-34, Example 7).

4. From a Prior Office Action:

5. In reference to claim 1, Gotsche discloses a coating agent, binder or film-forming excipient composition for solid substrates. Wherein the composition is comprised of:

Component A: a graft copolymer of polyvinyl alcohol and polyether (formed via polymerization of one vinyl ester of aliphatic C₁-C₂₄ carboxylic acids in the presence of a polyether), and

Component B: an additional polymer.

6. In reference to component A, it is noted that Gotsche discloses the genus, a graft copolymer of a vinyl ester of aliphatic C₁-C₂₄ carboxylic acids and polyether, however Gotsche specifically names and exemplifies a vinyl ester of acetic acid as a suitable vinyl ester of aliphatic C₁-C₂₄ carboxylic acids (10:5-11, Examples 1-12). As per MPEP §2131.02, a genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). Further it is held that one may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133

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USPQ 275 (CCPA 1962). The preferred embodiment of Gotsche is provided by the examples, wherein all of the examples are drawn to the claimed graft copolymer (Examples 1-12). Thus, it is clear that the claimed species is anticipated by the reference.

7. In reference to component B, Gotsche discloses that the graft copolymer can be combined with additional polymers; wherein the ratio of the graft copolymer to the additional polymer is 1:9 to 9:1. The examiner recognizes that Gotsche discloses, as an alternate embodiment, the inclusion of the additional polymer; as per MPEP § 2123, alternate embodiments constitute prior art. As discussed above, the reference anticipates the claimed graft copolymer species, thus anticipates, in an alternate embodiment, the claimed invention.

8. In reference to claims 2, 5, and 10, component B is a polymer; suitable compounds include the elected species of polyvinyl alcohols, polyvinylpyrrolidones and polyvinylpyrrolidone copolymers.

9. In reference to claim 20, regarding component C, Gotsche discloses that the graft copolymer can be applied in pure form or else together with conventional excipients to the substrate, including colored pigments, wherein the weight percentage of the conventional excipients in the composition is exemplified as 3 wt %.

10. In reference to claim 27-28, Gotsche discloses that solid substrates can be coated with the coating agent disclosed above. Additionally, the substrate can be a pharmaceutical formulation, such as tablets.

Claim Rejections - 35 USC § 103

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche as applied to claim 1 above, and further in view of Castillo (US 5091185).

13. Gotsche fails to disclose that component B is a polyvinyl alcohol having a degree of hydrolysis of between 80 and 90 mol%. Hence attention is directed towards the Castillo reference, which discloses solid pellets of the biologically active materials coated with a composition comprising polyvinyl alcohol (PVA), wherein the polycinyl alcohol preferably has a degree of hydrolysis greater than about 95% (col. 2, lines 35-55). Gotsche and Castillo are analogous art because they are from a similar problem solving area, coating solid pharmaceutical materials. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to replace Component B of Gotsche with the hydrolyzed PVA of Castillo. The motivation to do so, as taught by Castillo, is employ the hydrolyzed PVA in order to effectively control the release of the active material after implantation to provide a more uniform rate of delivery over a longer period of time as compared to uncoated pellets (col. 2, lines 35-55).

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche (WO/00/18375) as applied to the claims above, and further in view of Babaian et al. (US 4842854).

15. Gotsche fails to disclose that component B comprises vinylpyrrolidone-(meth)acrylate copolymers. Thus attention is directed towards the Babaian reference, which is drawn to pharmaceutical film composition. The film of Babaian comprises vinylpyrrolidone, or a copolymer thereof with an acrylate, wherein the film is recognized as a biologically soluble and resolvable carrier. Specifically, the disclosed film is mouth mucosa soluble, swellable and resolvable polymeric film-forming carrier (col. 16, line 61 to col. 17, line 4; claim 1).

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16. It is noted that, for component B, Gotsche discloses that suitable film formers include polyvinylpyrrolidone and polyvinylpyrrolidone copolymers. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize vinylpyrrolidone-acrylate copolymer as component B in the invention of Gotsche, as taught by Babaian. The motivation includes utilization of a mouth mucosa soluble, swellable and resolvable polymeric film-forming carrier.

17. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gotsche (WO/00/18375).

18. Gotsche applies as above, however, fails to disclose that component C is present in at least 5 wt % of the composition. It is noted that Gotsche exemplifies the weight percentage of the conventional excipients (component C) in the composition as 3 wt % (Example 7 and 8). However, Gotsche discloses that the examples of conventional excipients include white pigments such as titanium dioxide which increase the hiding power, in addition to mentioning other suitable excipients and their advantages (page 19, lines 10-21). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to increase the amount of any of the conventional excipients mentioned by Gotsche in order increase the respective advantages, such as increase the hiding power, increase non-sticking, or to further improve the wetting characteristics. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

19. Applicants have argued that Gotsche fails to anticipate the claimed invention. Applicants have argued that the genus for component A, as disclosed by Gotsche, is insufficient to anticipate

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the claimed species within the genus. As discussed above, Gotsche explicitly discloses preference to the claimed graft copolymer species.

20. Applicants have further argued that Gotsche discloses the possibility of including additional polymers (component B) in the composition. As discussed above, this disclosure is an alternate embodiment of the reference, which combines component A and B, and thus anticipates the claim.

21. Applicants have further argued that the selection of the additional polymers (component B) is from a broad genus; however, in reference to claims 5 and 10, as noted above, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Additionally, the claimed species are disclosed with sufficient specificity in the reference, the selection is drawn from a group of eleven components. Selection from a group of eleven components is not considered sufficiently limited. Thus, the Gotsche's disclosure of the named species anticipates the species of claims 5 and 10.

22. In reference to the 103(a) rejection of claim 7, applicant has argued that no teaching, suggestion, or motivation exists to combine the references. In support of their argument, applicants have stated that Gotsche is drawn to coatings with the instant release of the active material, wherein the Castillo reference is drawn to extended release coatings. The examiner has thoroughly considered the arguments and support provided, and concludes that the rejection is valid. The invention of Gotsche is drawn to a coating agent, binder and/or film-forming excipient in pharmaceutical presentations (1:2-4). Although, Gotsche discusses the instant release of the active material, the reference teaches that the rate of release of the active ingredient can be adjusted by the film coating (1:19-21). Thus, Gotsche teaches modification of the rate of release and the Castillo reference, as discussed in the rejection above, teaches a specific component utilized to control the rate of release of a film coating on a pharmaceutical presentation.

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23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Haider whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Saira Haider
Examiner
Art Unit 1711



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